

Application Number 10/813,307  
Amendment dated May 7, 2007  
Responsive to Office Action mailed February 8, 2007

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**REMARKS**

This amendment is responsive to the Final Office Action dated February 8, 2007.

Applicant has amended claims 1 and 29. Claims 67 and 68 have been added. Claims 1-5, 17-32, 41-47, and 67-68 are pending.

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**Claim Rejection Under 35 U.S.C. § 102**

In the Final Office Action, claims 1, 17-18, 25-28, 29, 41, 43, and 45-47 are rejected under 35 U.S.C. 102(b) as anticipated by Silverstein et al. (US 5,247,938), which is referred to hereafter as Silverstein. Claims 1-3, 18-20, 24-27, 29-31, and 45-46 are rejected under 35 U.S.C. 102(b) as anticipated by Kilcoyne et al. (US 6,689,056), which is referred to hereafter as Kilcoyne. Claims 1-3, 24-31, and 45-47 are rejected under 35 U.S.C. 102(e) as anticipated by Colliou et al. (US 7,020,531), referred to herein as Calliou.

Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Silverstein, Kilcoyne, and Colliou all fail to disclose each and every feature of the claimed invention and provides no teaching that would have suggested the desirability of modification to include such features.

Independent claim 1 as amended requires a device housing sized for introduction into and residence completely within the body lumen and a fixation mechanism to attach the device housing to a surface within the body lumen. Claim 1 also requires a controlled detachment mechanism mechanically actuated to selectively detach the device housing from the surface of the body lumen. The medical device remains completely within the body lumen until after the device is detached from the surface. Independent claim 29 also requires similar elements. Each reference of Silverstein, Kilcoyne, and Colliou fails to duplicate the required elements of independent claims 1 and 29.

With regard to Silverstein, the Examiner indicated that Silverstein discloses elements of the claimed invention. The Examiner characterized the medical device as probe 40, the fixation mechanism as "suction chamber 50 which gently attaches to the mucosa,"<sup>1</sup> and the detachment mechanism as using service loop 72, vacuum lumen 52, and probe head 40 "in which suction is

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<sup>1</sup> Silverstein et al., Col. 4, ll. 40-43.

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used for maintaining the probe on the intestinal wall.”<sup>2</sup> However, the Silverstein device fails to disclose two elements required in the independent claims as amended.

First, the Silverstein device does not remain completely within the body lumen until after the device is detached from the surface. Silverstein teaches that “service loop 72 is made sufficiently long that it can remain attached to the suction source until the tip of the endoscope 92 clears the mouth, the anus, or other opening of the digestive tract.”<sup>3</sup> In addition, Silverstein discloses that “The service loop 72, coupled to the probe 40 or a plurality of probes 40, arranged either in series or parallel, is brought out of the surgical opening”<sup>4</sup> in some embodiments. In other words, the Silverstein device requires service loop 72 to exit the patient at all times. Therefore, the Silverstein device does not remain completely within the body lumen until after the device is detached from the surface.

Second, the Silverstein device fails to include a controlled detachment mechanism mechanically actuated to selectively detach the device housing from the surface of the body lumen. Silverstein suggests several methods for attaching probe 40, such as “a temporary glue,” “suction chamber 50,” and “a depressible membrane 49.” However, nowhere does Silverstein suggest a mechanically actuated controlled detachment mechanism of probe 40 that is capable of removing the attached probe 40. Silverstein discusses removing probe 40 when “the suction is disengaged”<sup>5</sup> through service loop 72, “air pressure [is] applied through the suction lumen,”<sup>6</sup> the substance is “biodegradable and automatically release[s] the probes after a period of time,”<sup>7</sup> or “it may be necessary to surgically remove the suture and remove the probe.”<sup>8</sup> Biodegradable materials are not mechanically actuated, as they are subject to chemical degradation in the surrounding environment. None of these methods for removing probe 40 anticipate a mechanically actuated controlled detachment mechanism, as required by independent claims 1 and 29.

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<sup>2</sup> Silverstein et al., Col. 6, ll. 1-2.

<sup>3</sup> Silverstein et al., Col. 6, ll. 2-6.

<sup>4</sup> Silverstein et al., Col. 7, ll. 15-18.

<sup>5</sup> Silverstein et al., Col. 12, l. 38.

<sup>6</sup> Silverstein et al., Col. 12, ll. 40-41.

<sup>7</sup> Silverstein et al., Col. 12, ll. 47-48.

<sup>8</sup> Silverstein et al., Col. 12, ll. 51-52.

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With regard to Kilcoyne, the Examiner indicated that Kilcoyne disclosed the elements of the claimed invention. Applicant interprets the Examiner's characterization of the device housing as monitor 18, the fixation mechanism as deployment catheter 138, attachment cavity 124, and tissue pin 164, and the detachment mechanism as "materials in [an alligator] clip dissolve ... the clip will break free of the esophagus 30."<sup>9</sup> Applicant submits that the Examiner is inadvertently combining multiple embodiments disclosed by Kilcoyne. Nonetheless, Applicant disagrees with the Examiner because none of the Kilcoyne devices teach or suggest the elements of independent claims 1 and 29 as amended.

Kilcoyne fails to teach or suggest a controlled detachment mechanism that is mechanically actuated. Kilcoyne states a clip "can hold the monitor in place by capturing, or "pinching," the mucosa and submucosa of the esophagus 30 between its arms or "jaws."<sup>10</sup> The detachment of the clip is described "As materials in the clip dissolve, the tension in the clip that causes it to hold onto, or pinch, the esophagus 30 will eventually decrease, and the clip will break free of the esophagus 30."<sup>11</sup> The dissolvable materials in the clip are subject to chemical degradation within the environment. The Kilcoyne device detachment mechanism is at the mercy of the surrounding environment in order to detach from esophagus 30. In this manner, the clip disclosed by Kilcoyne cannot be a controlled detachment mechanism that is mechanically actuated, as required by claims 1 and 29.

With regard to Colliou, the Examiner indicated that Colliou disclosed the elements of the claimed invention. Colliou discloses device 20 that may be "attached to the stomach wall."<sup>12</sup> Device 20 may be attached to the stomach wall with needle 524, wherein "the knob 530 enables an instrument to grasp and advance or retract the needle 524 into or from the housing 521."<sup>13</sup> In this manner, "a grasping instrument 556 requires grasping jaws 557"<sup>14</sup> to attach and detach device 20 from the stomach wall. Applicant respectfully submits that Colliou fails to teach or suggest the elements of claims 1 and 29 as amended.

<sup>9</sup> Kilcoyne et al., Col. 9-10, ll. 66-2.

<sup>10</sup> Kilcoyne et al., Col. 9, ll. 58-61.

<sup>11</sup> Kilcoyne et al., Col. 9-10, ll. 66-2.

<sup>12</sup> Colliou et al., Col. 12, ll. 44.

<sup>13</sup> Colliou et al., Col. 11-12, ll. 67-2.

<sup>14</sup> Colliou et al., Col. 13, ll. 1-2.

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Colliou fails to disclose a controlled detachment mechanism mechanically actuated to selectively detach the device housing from the surface of the body lumen, where the medical device remains completely within the body lumen until after the device is detached from the surface. The Colliou system requires grasping instrument 556 and grasping jaws 557 to "advance or retract the needle 524,"<sup>15</sup> e.g., detach needle 524 and device 520 from the stomach. In this manner, "grasping instrument 556 grasping instrument 556 with grasping jaws 557 at its distal end extends through the endoscope 110."<sup>16</sup> Since "endoscope 110 is passed through the mouth 101, pharynx 102, into the esophagus 103 and into the stomach 100,"<sup>17</sup> the detachment mechanism does not remain completely within the body lumen until after the device is detached from the surface. Applicant respectfully submits that Colliou fails to teach or suggest the elements of claims 1 and 29 as anebded.

Dependent claims 2-3, 17-20, 24-28, 30-31, 41, 43, and 45-47 are dependent upon independent claims 1 and 29, and are allowable for at least the reasons set forth with respect to claims 1 and 29.

The disclosures of Silverstein, Kilcoyne, and Colliou all fail to disclose each and every limitation set forth in claims 1-3, 17-20, 24-31, 41, 43, and 45-47. For at least these reasons, the Examiner has failed to establish anticipation of Applicant's amended claims 1-3, 17-20, 24-31, 41, 43, and 45-47 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

#### **Claim Rejection Under 35 U.S.C. § 103**

In the Office Action, claims 21-23, 42 and 44 are rejected under 35 U.S.C. 103(a) as unpatentable over Kilcoyne. Claims 21 and 42 are rejected under 35 U.S.C. 103(a) as unpatentable over Kilcoyne in view of Christopherson et al. (US 6,021,352). Claims 22 and 44 are rejected under 35 U.S.C. 103(a) as unpatentable over Kilcoyne in view of Cimochowski et al. (US 5,967,986). Claim 23 is rejected under 35 U.S.C. 103(a) as unpatentable over Kilcoyne in view of Imran et al. (US 6,535,764).

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<sup>15</sup> Colliou et al., Col. 12, ll. 1-2.

<sup>16</sup> Colliou et al., Col. 13, ll. 1-3.

<sup>17</sup> Colliou et al., Col. 11, ll. 15-16.

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Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 21-23, 42 and 44 are dependent upon independent claims 1 and 29. As described above, independent claims 1 and 29 are allowable over all of the references of Silverstein, Kilcoyne and Colliou. Therefore, claims 21-23, 42 and 44 are allowable for at least the same reasons.

The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention. In regard to independent claims 1 and 29, no combination of the applied references provides motivation to someone of ordinary skill in the art to duplicate the mechanically actuated controlled detachment mechanism or that the medical device remains completely within the body lumen until after the device is detached from the surface, as required by Applicant's claims.

For at least these reasons, the Examiner has failed to establish that claims 21-23, 42 and 44 are prima facie obvious under 35 U.S.C. 103(a) over the cited references. Withdrawal of this rejection is requested.

**Rejection for Obviousness-type Double Patenting:**

The Examiner rejected claims 1-3, 16, 18-19, 24-27, 29-31, 45-46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,689,056.

The Examiner provisionally rejected claims 1, 18, 24-27, 29, 45-46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-17, 62-87 of copending Application No. 10/833,776.

The Examiner provisionally rejected claims 1-3, 18, 24-27, 29-31, 45-46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-11, 13-16, 55-58, 61-66 of copending Application No. 10/687,296.

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The Examiner provisionally rejected claims 1-3, 16, 18, 19, 24-27, 29-31, 45-46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-58, 66, 69, 71, 73 of copending Application No. 10/896,533.

The Examiner provisionally rejected claims 1-3, 18, 24-31, 45, 46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/835,425.

A Terminal Disclaimer accompanies this Amendment. The disclaimer is made to expedite issuance and is not intended as an admission that any claim of the present application is the same or an obvious variant of those of U.S. Patent No. 6,689,056 and U.S. Application Nos. 10/833,776, 10/687,296, 10/896,533, and 10/835,425. This disclaimer obviates the double patenting rejection and places claims 1-5, 17-32 and 41-47 in a condition for allowance.

#### **Allowable Subject Matter**

In the Final Office Action, the Examiner indicated that claims 4-5 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant appreciates the allowance of claims 4-5 and 32 if written in independent form. Applicant has not incorporated elements from claims 4, 5 or 32 into their respective independent claims; however, Applicant has added new independent claim 67 and corresponding dependent claim 68. Independent claim 67 includes elements of claims 1 and 4, and dependent claim 68 includes elements of claim 5. Applicant reserves the right to rewrite claim 32 in its independent form at a later time.

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### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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By:

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